6.0 510(k) Summary

In accordance with the provisions of the Safe Medical Device Act of 1990, Philips Healthcare Informatics, Inc. is providing a summary of Safety and Effectiveness information regarding the IntelliSpace PACS 4.x software.

6.1 Company Identification

Philips Healthcare Informatics, Inc.

4100 East Third Avenue, Suite 101

Foster City, CA 94404

Registration Number: 2954704

6.2 Contact Person

Victoria S. Mackinnon

Director of Quality and Regulatory

Telephone: 650-293-2373

Fax: 650-293-2301

6.3 Preparation Date

April 25, 2011

6.4 Identification of Product and Classification

Device Trade Name: IntelliSpace PACS 4.x

Classification Name: Picture Archiving and Communications System

Classification Panel: Radiology

CRF Section: 892.2050

Device Class: II

Product Code: LLZ

6.5 Substantial Equivalence

Manufacturer: Stentor, Inc., a Philips Medical Systems Company

Model: iSite PACS v4.x

510(k) Number: K063267

6.6 Device Description and Intended Use

IntelliSpace PACS 4.x is an image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians.

The system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, communication and storage.

IntelliSpace PACS 4.x supports receiving, sending, printing, storing and displaying studies received from the following modality types via DICOM: CT, MR, NM, US, XA, PET, DX, DR, RF, RT, MG, SC, VL, as well as hospital/radiology information systems.

6.7 Software Development

Philips Healthcare Informatics certifies that the IntelliSpace PACS 4.x software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance. The software developed for this product is used to provide diagnostic-quality images and associated information to the intended users.

6.8 Performance Testing

The software design was verified to ensure design output met functional and operational requirements. The verification results showed that the proposed device met the expectations in safety, performance and reliability. Additionally, performance was evaluated and interoperability and compatibility testing was conducted to confirm conformance to DICOM, HL7 and IHE standards.

The validation testing was performed at the system level with production ready software under an actual or simulated environment in which the device is expected to be used. The validation testing covered software and risk management validation. The validation testing results confirmed that the proposed device met user needs and intended use.

Testing included regression testing to legacy features and demonstrated substantial equivalence to earlier versions of this product.

6.9 Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device. It is the user's responsibility to ensure that

display quality, environmental lighting and other possible distractions are consistent with the clinical environment. The hardware components specified are all "off the shelf" computer components.

Conclusion:

IntelliSpace PACS 4.x is substantially equivalent in design and intended use to the predicate device, iSite PACS v4.x, which includes diagnostic radiological workstations, PACS and image management. Any differences between the IntelliSpace PACS 4.x software and the predicate device have no significant influence on safety or effectiveness. Therefore, IntelliSpace PACS 4.x raises no new issues of safety or effectiveness from the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Phillips Healthcare Informatics
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

JUL 28 2011

Re: K111804
Trade/Device Name: IntelliSpace PACS 4.x
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 24, 2011
Received: June 27, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

5.0 Indications for Use Form

510(k) Number (if known): Unknown K111804

Device Name: IntelliSpace PACS 4.x

Indications for Use:

IntelliSpace PACS 4.x is an image management system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians.

The system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, communication and storage.

Lossy compressed mammographic images and digitized screen images must not be reviewed for primary image interpretations.

Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111804

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